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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,267	12/15/2003	Michael Berthon-Jones	3869-020	6196

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EXAMINER

MATTER, KRISTEN CLARETTE

ART UNIT PAPER NUMBER

3771

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/737,267

Applicant(s)

BERTHON-JONES, MICHAEL

Examiner

Kristen C. Matter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12/15/06.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br/>Paper No(s)/Mail Date <u>12/15/03 and 12/30/03</u>.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)<br/>Paper No(s)/Mail Date. _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____</p> |
|---|--|

## **DETAILED ACTION**

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Australia on 11/05/93. It is noted, however, that applicant has not filed a certified copy of the PM2246 application as required by 35 U.S.C. 119(b). Please also note that continuing data provided by applicant is not consistent with PTO records. Appropriate verification of continuing data is needed for claimed priority dates.

### ***Information Disclosure Statement***

The information disclosure statements filed 12/15/06 and 12/30/06 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered as marked on the attached IDS.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Recitation of the term "said determining step" on line 2 of the claim is considered vague because it is unclear as to which determining step the term is referring to (i.e., determining the patient's cardiac rate from claim 3 or determining airway patency from claim 1).

Claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Recitation of the term "determining control a detection of a component" on line 3 of the claim renders the claim indefinite because it is unclear what the applicant is claiming.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 39, 45, and 50 rejected under 35 U.S.C. 103(a) as being unpatentable over Biondi et al. (US 5,377,671). Biondi et al. teaches a cardiac synchronous ventilation which comprises a controller 20, a ventilation valve with a gas source, vacuum source, and pressure and flow sensors which measure pressure and flow of gas supplied to and extracted from the patient, and a cardiac cycle monitor (see column 3, lines 10-17). The cardiac monitor is depicted as an electrocardiogram, however, Biondi et al. acknowledges that that other cardiac cycle monitors may be used as well (see column 3, lines 25-30). Based on the output signal from the cardiac

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cycle monitor, the controller 20 analyzes the signal produced to determination duration of the various cardiac cycle periods and generates a ventilation valve controller signal for delivering breathing gas to a patient (see column 3, lines 30-40).

Regarding claim 39, Biondi et al. does not teach determining airway patency and specifically detecting the presence of cardiogenic airflow. However, the device taught by Biondi et al. is capable of performing the analysis disclosed by the applicant. The electrocardiogram can be used to determine the presence of cardiogenic airflow from a patient and the controller could be programmed to deliver pressure to the patient based on this analysis. It would have been obvious to one of ordinary skill in the art at the time the invention was filed to have used the method disclosed by the applicant with the apparatus taught by Biondi et al. for treatment of sleep apnea with positive pressure therapy. Furthermore, at the time the invention was filed the relationship between cardiogenic oscillations as a possible indication of sleep apnea was known in the art as can be seen in cited reference Watson et al. (US 4,777,962).

Regarding claim 45, Biondi et al. does not teach that the processor (controller) has instructions for determining airway patency by detection of cardiogenic airflow. However, the apparatus taught by Biondi et al. is structurally the same and could be programmed with instructions for determining airway patency. Please see above arguments regarding claim 39.

Regarding claim 50, Biondi et al. does not teach an analysis of airflow to detect the presence of cardiogenic airflow. However, the apparatus taught by Biondi et al. would be capable of performing the same function as the apparatus disclosed by the applicant. Please see above arguments regarding claim 39.

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Claims 40-44, 46-49, and 51-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biondi et al. and further in view of Rapoport (US 5,335,654). The teachings of Biondi et al. are discussed above. Rapoport teaches a method and apparatus for continuous positive airway pressure (CPAP) treatment of obstructive sleep apnea. Inspiratory airflow is measured to detect deviations in the airflow waveform that correspond to flow limitation in the air supplied to the patient by a processor (see column 2, lines 40-45). The system has a program that decreases the airflow in the absence of airflow limitation and increases the airflow in the presence of a detection of the airflow limitation (see column 2, lines 55-60).

Regarding claims 40 and 41, Rapoport does not teach cardiogenic airflow as an indication of flow limitation. However, Rapoport does teach that the disclosure taught is not limited to any particular techniques for determining the presence of a flow limitation from the airflow waveform (see column 5, lines 50-55). As mentioned above, at the time the invention was filed the relationship between cardiogenic oscillations as a possible indication of sleep apnea was known in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was filed to have combined the ventilation apparatus taught by Biondi et al. with the program to increase and decrease airflow supplied to the patient as needed based on the detection of airflow limitation for the treatment of sleep apnea.

Regarding claim 42, Rapoport does not teach a filter specifically. However, it would have been obvious to one of ordinary skill in the art at the time the invention was filed to have had a filtering means to reject unwanted components of respiration or noise since filters are well known in the art as a means for eliminating unwanted noise with use of electrical transducers.

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Regarding claim 43, Rapoport does not teach a Fourier transform. However, it would have been obvious to one of ordinary skill in the art at the time the invention was filed to have used a Fourier transform, as Fourier transforms are well known in the art for evaluating frequency components of signals. Furthermore, applicant acknowledges in the disclosure that use of the Fourier transform is not critical, and that any mathematical method of detecting rhythmic oscillation with a frequency of the anticipated heart rate and its first harmonic will suffice.

Regarding claim 44, the apparatus taught by Biondi et al. determines patient's cardiac rate from the electrocardiogram and the controller calculates the breath rate from this input (see column 3, lines 50-55). Please see rejection for claim 39 above.

Regarding claim 46, Rapoport does not teach a turbine. However, it would have been obvious to one of ordinary skill in the art at the time the invention was filed to have used a turbine to supply breathable gas with the determination of an airflow limitation in the combined device taught by Biondi et al. and Rapoport (see rejection for claim 45 above) because turbines are well known in the art for delivering gas to patients in respiratory devices as can be seen in the cited reference by De Vuono et al. (US 4,989,595).

Regarding claim 47, please see rejection for claim 40 above.

Regarding claim 48, please see rejection for claim 43 above.

Regarding claim 49, Biondi et al. does not teach a pulse oximeter for determining cardiac rate. However, as noted Biondi et al. does teach that other cardiac cycle monitors may be used. It would have been obvious to one of ordinary skill in the art at the time the invention was filed to have used a pulse oximeter instead of, or in conjunction with, the electrocardiogram taught by Biondi et al. for determining cardiac rate and generating an air flow signal (breath rate) in the

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combined device taught by Biondi et al. and Rapoport (see rejections for claims 44 and 45 above) as pulse oximeters are well known in the art as a means for measuring cardiac rate as seen in cited reference Miles (US 5,353,788).

Regarding claim 51, please see rejections for claims 40 and 46 above.

Regarding claim 52, please see rejections for claims 41 and 47 above.

Regarding claim 53, please see rejections for claims 43 and 48 above.

Regarding claim 54, please see rejections for claims 44 and 49 above.

### *Conclusion*

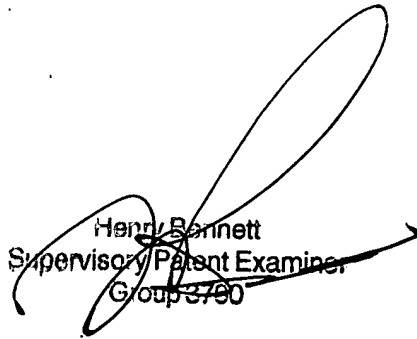
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-4794. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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